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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,017	02/14/2002	Ishay Ostfeld	OSTFELD1	5626

7590 06/23/2003  
BROWDY AND NEIMARK, P.L.L.C.  
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Washington, DC 20001

EXAMINER

KONTOS, LINA R

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/074,017

Applicant(s)

OSTFELD ET AL.

Examiner

Lina Kontos

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 22,23,28,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18,21,24-27,30 and 31 is/are rejected.
- 7) ☒ Claim(s) 19,20 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: \_\_\_\_\_

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***Election/Restrictions***

***I.***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22,24-27,29-31 drawn to a cover for a medical device, classified in class 604, subclass 171.
- II. Claims 22,23 drawn to method of making a cover, classified in class 604, subclass 171
- III. Claims 28,32,33 drawn to system for making the cover, classified in class 264, subclass 635

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cover of claim 1 can be made by many other methods depending on the material

Inventions III and I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product can be made by a different apparatus depending on the desired material of the cover.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jay Fincklestein on June 2 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22,24-27,29-31.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 22,23,28,32,33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Specification**

2.

The disclosure is objected to because of the following informalities:

The brief description of drawings does not contain a description of every figure.

The use of the word "mandrill" throughout the specification is inappropriate. Examiner has considered this word to be a typographical error and the correct word to be either mandril or mandrel, meaning a spindle or an axle used to secure or support material being machined or milled, and opposed to "mandrill," as printed, which is a baboon of Western Africa.

Appropriate correction is required.

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### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3.

Claims 1-3,8-12,25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wepsie.

Wepsie teaches an inner cover (11) for a catheter manufactured from rubber. The inner cover is impermeable (column 1, line 58) and contains an antibacterial substance (column 1, line 62) that is delivered to the body through the permeable outer layer of the catheter. The inner cover has grooves (13-18) that provide the surface with a rough quality.

4.

Claims 1,2,4,7,9-11,13,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Coulter.

Coulter teaches a catheter system with two exterior covers (4,5) wherein the lubricating medium between the covers contains an antibiotic (column 5, lines 4-6,10-13).

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5.

Claims 1,2,4-11,14,18,21 are rejected under 35 U.S.C. 102(e) as being anticipated by Holman et al.

Holman et al. teaches a balloon catheter or a stent delivery system (110) with an expandable distal portion and a protector means for the balloon and/or stent. The protector means comprises two removable sleeves (128,140), with the inner sleeve (128) covering the stent (124) and the outer sleeve (140) positioned over the inner sleeve (128). The covers may be formed from the same “any suitable low-friction material” (page 10, column 1, line 2), or different materials, such as the inner sleeve may be made from a more lubricious material, and the outer cover from a shape memory metal. [0125-0126]. The covers are held in place on the system by their own elastic forces. The inner cover has a slit extending lengthwise to facilitate easy removal – the outer cover placed over the inner cover holds the adjoining slit sides in communication with each other.

6.

Claims 1,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kusleika.

Kusleika teaches a catheter and dilatation device comprising a delivery sheath and balloon extending over the catheter. As depicted in Figures 4-7, the cover (22) is in contact with the catheter and balloon surface, and when the balloon is expanded and then deflated, the cover sheath becomes detached from the surface.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7.

Claims 15,16,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman et al. in view of Chin.

Holman et al., as described above, teaches a dual cover for a stent delivery system.

Chin teaches a perforated sheath for an aortofemoral bypass graft.

It would have been obvious to one skilled in the art at the time of the invention to include perforations along the sheath to enable the sheath to have been held onto the surface more securely and then to facilitate easy removal.

8.

Claims 17,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman et al. in view of Maloney et al.

Holman et al., as described above, teaches a dual cover for a stent delivery system.

Maloney et al. teaches a slitter comprising a blade used to slit an introducer for removal from a catheter.

It would have been obvious to one skilled in the art at the time of the invention to incorporate this slitter for removal means of the protective cover for the catheter system instead of having to manufacture a cover with a preformed slit.

***Conclusion***

***9.***

Claims 19,20,29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***10.***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5,752,937 describes a medical introducer for inserting a catheter into a patient wherein the introducer is removed by the user pulling on a ring that is attached to a strengthening strip running the length of the introducer, thus splitting the introducer.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK  
June 10, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700